



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,209	10/05/2001	Barry Barton	P32085	8328

20462 7590 12/17/2003

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
----------	--------------

1652

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,209	BARTON ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-22 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) 21,22 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20,29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (mailed on June 10, 2003), Applicants filed an amendment and response received on September 15, 2003. Said amendment cancelled Claim 23, amended Claims 15, 16, and 19, and added new Claims 29 and 30. Thus, Claims 15-22 and 24-30 are pending in the instant Office action.

Election

2. Claims 15-22 and 24-30 are pending in the instant application. Claims 21, 22, and 24-28 are withdrawn from further consideration as non-elected inventions. Claims 15-20 and 29-30 will be examined herein.

Priority

3. As previously noted, the instant application is 371 application of International Application No. PCT/GB99/02301 filed on July 15, 1999 and is granted the benefit of priority for the foreign application 9815666.4 filed in the Great Britain on July 17, 1998.

Withdrawn - Objections to the Specification

4. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicants' amendment.
-

Withdrawn - Claim Objections

5. Previous objection to Claim 23 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.

6. Previous objection to Claim 19 for having improper English is withdrawn by virtue of Applicants' amendment.

Maintained - Claim Rejections - 35 U.S.C. § 102

7. Previous rejection of Claims 15-20 under 35 U.S.C. § 102(b) as being anticipated by Baggaley *et al.* (WO 94/12654) is maintained; Claims 29-30 are added to this rejection for the reasons noted below. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants "do not agree" that the protein taught by Baggaley *et al.* for use in the methods has, in fact, the inherent structure of SEQ ID NO:2. The Examiner disagrees. The combination of the same source and the same function necessarily indicate the same protein is used by Baggaley *et al.*

Applicants further agree that their amendments to the claims are as the Examiner suggested and obviate the rejection; this is not the case. The Examiner specifically noted that

"claims drawn to a method using steps of (1) producing an enzyme having the sequence shown in SEQ ID NO:2 in a host cell using a vector comprising **SEQ ID NO:1**, and (2) contacting formula II or III with said enzyme to prepare compound I or IV is neither anticipated nor made obvious by the prior art. The Examiner specifically notes that the production of the protein in a host cell must be an *explicit step*, and not implicit as found in pending Claim 23. While Baggaley *et al.* do teach the isolated protein, they do not teach the isolated DNA

Art Unit: 1652

encoding said protein, without or without sequence information. Thus, methods using the DNA are not anticipated or rendered obvious by explicit sequence disclosure or by isolation of an "unsequenced" product. Therefore, claims drawn to using the DNA that is SEQ ID NO:1 cannot be anticipated or rendered obvious by Baggaley *et al.*

Additionally, the Examiner reiterates that SEQ ID NOs: 1 and 2 are not novel in the art based on the disclosure of Jensen. However, in Jensen, no function is assigned to the protein. Thus, no motivation to combine SEQ ID NO:2 with any particular substrate can be set forth. Therefore, Jensen does not strengthen the above art rejection because knowing the sequence of the protein is not relevant against the claims as pending.

The amendment requires only that the isolated polypeptide be produced from a polynucleotide.

This step is also inherent in Baggaley *et al.* since the polypeptide is produced from a polynucleotide in the cell naturally. Without the inclusion of isolated polynucleotides and vectors and host cell, as suggested by the Examiner previously, the art rejection is maintained.

Summary of Pending Issues

8. The following is a summary of the issues pending in the instant application:
 - a) Claims 15-20 and 29-30 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Baggaley *et al.*

Conclusion

9. Claims 15-20 and 29-30 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).


Art Unit: 1652

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


PONNATHAPUACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Kathleen M Kerr, Examiner 1652
December 8, 2003